

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 16, 2005, from 8:30 a.m. to 5:15 p.m. and on November 17, 2005, from 8:30 a.m. to 5:30 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Christine Walsh or Denise Royster, Center for Biologics Evaluation and Research (HFM-71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting.

Agenda: On November 16, 2005, the committee will hear presentations and discuss the use of Madin-Darby Canine Kidney Cells for manufacture of

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Inactivated Influenza Vaccines. On November 17, 2005, the committee will discuss developing new Pneumococcal Vaccines for U.S. licensure for adults.

Procedure: On November 16, 2005, from 8:30 a.m. to 5:15 p.m. and on November 17, 2005, from 10 a.m. to 5:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 9, 2005. Oral presentations from the public will be scheduled on November 16, 2005, between approximately 1:45 p.m. and 2:15 p.m. and on November 17, 2005, between approximately 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 9, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

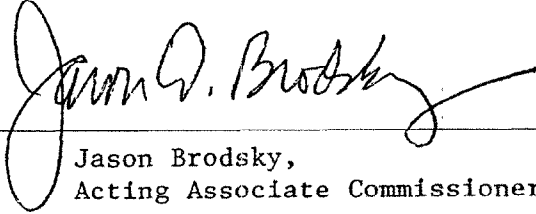
Closed Committee Deliberations: On November 17, 2005, from 8:30 a.m. to 9:55 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)).

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: 10-18-05
October 18, 2005.



Jason Brodsky,
Acting Associate Commissioner for External Relations.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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